

Chairman Tom Davis
Opening Statement
“Medical Device Safety: How FDA Regulates the Reprocessing of Supposedly
Single-Use Devices”
September 26, 2006

Good morning. Welcome to today’s hearing on the Food and Drug Administration’s (FDA) regulation of reprocessed single-use devices (S.U.D.). The purpose of this hearing is to assess FDA’s oversight of the reprocessing industry and to determine what, if any, additional measures are needed to ensure reprocessed SUDs are effective and safe. FDA is responsible for approving these devices. Manufacturers choose to submit applications for single-use only designation as opposed to a multi-use designation. FDA, however, allows reprocessed SUDs to be marketed if they are “substantially equivalent” to the original device.

Many of you may not be aware that several commonly used medical devices are cleaned and resterilized to be used by hospitals more than once. Devices such as catheters, biopsy forceps, and surgical tools are often designated for one-time use, but hospitals routinely pay to have them reprocessed to cut costs and reduce medical waste. For example, new biopsy forceps can cost \$60, yet reused forceps can cost as little as \$15. Savings from use of reprocessed devices can be significant.

Original device manufacturers have said, however, they cannot guarantee the safety of SUDs once they are reprocessed and reused. Reprocessors contend there is no sufficient or credible evidence to indicate the use of reprocessed medical devices is riskier than the use of new ones. Hospitals may save overhead costs but is it at a cost to patient health? This is just one of the many questions we’ll be asking our witnesses today.

The Committee’s interest in this issue began with a series of articles in the Washington Post that reported many instances of patient injury associated with the use of defective or unsterile reprocessed devices. Mr. Waxman and I wrote to the FDA asking for information on device safety regulation and the adequacy of adverse event data. The FDA responded that the data in hand did not establish a clear causal link between reprocessed devices and subsequent adverse health effects. But we need to know whether that’s because the reprocessed devices are safe or because MedWatch, the adverse event monitoring system, is too passive or insensitive to capture subtle but potentially deadly trends.

Today’s hearing will question whether FDA’s current MedWatch reporting system can accurately capture adverse events resulting from reprocessed devices. We’ll ask FDA how new labeling requirements, under the Medical Device User Fee and Modernization Act, are working to help improve the MedWatch system. Effective last month, reprocessed devices are required to be stamped or tagged with a label indicating they’ve been reprocessed. Previously, only the packaging was required to identify the

device as reprocessed, and most doctors were unaware devices were reprocessed as packaging is often removed prior to use in the operating room.

I realize some of our witnesses will say it's too early to clearly determine what impact the new labeling requirement will have on adverse event reporting—and that's OK. Today's hearing will not be the Committee's final look at this issue. Mr. Waxman and I have asked GAO to update its June 2000 report on SUDs. GAO's initial report found little harm from reuse but recommended additional oversight by the FDA. Because FDA regulation of the industry has increased significantly since 2000, the Committee asked GAO to specifically examine the safety of SUD reprocessing, the adequacy of FDA's oversight, and how reprocessed SUDs compare to original devices. GAO has accepted this request but has not yet initiated work.

Before we move to our first panel, I have to express my disappointment in the original device manufacturing industry. We have no device makers testifying today because they preferred to speak through their trade association, AdvaMed. Specifically, C.R. Bard, a company from Murray Hill, New Jersey, was invited to testify but declined to appear before the Committee. We would have preferred to have direct testimony from companies so they would be able to provide specific examples and commentary regarding their specific devices. Despite the Committee's disappointment with the lack of an original device manufacturer witness, we will continue our discussions with those companies. We have the reprocessors represented by SterilMed and Ascent Healthcare Solutions, the two largest companies in the business, ready to testify today and I thank them for appearing. I look forward to the testimony today from both panels on this important issue.